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Long-term Results of Above Knee Femoro-popliteal Bypass Depend on Indication for Surgery and Graft-material

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Objective. *To determine the long-term results of above-knee femoro-popliteal bypass with autologous saphenous vein (SV) or expanded polytetrafluoroethylene (ePTFE) in routine surgical practice.*
Methods. *Data from the Swedish vascular registry, Swedvasc was reviewed retrospectively. Patients with bypass surgery in 1996 and 1997 were assessed 5–7 years later. Data were gathered from the case-records and from clinical follow-up. The composite endpoint of graft failure included death within 30 days, occlusion, major amputation, extension of the graft to below-knee position and removal of an infected graft. Kaplan–Meier curves and Cox' proportional hazard ratios were calculated.*
Results. *Four hundred and ninety-nine patients undergoing bypass for critical limb ischemia (CLI) (56%) or claudication (44%), SV (28%) or ePTFE (72%), were included. There were no significant differences in patient characteristics between patients with SV or ePTFE. CLI and ePTFE were risk factors for graft failure. For patients with both claudication and CLI SV grafts yielded better long-term results than ePTFE grafts* ($p < 0.03$) *and* ($p < 0.003$), *respectively. Symptom aggravation after graft occlusion was almost exclusively restricted to ePTFE grafts.*
Conclusions. *Femoro-popliteal bypass above-knee with SV gives good long-term results, especially for claudication. ePTFE grafts cannot be recommended in claudicants, since occlusion occurs often and frequently leads to CLI.*

Keywords: Popliteal artery; Intermittent claudication; Critical ischemia; Blood vessel prosthesis implantation; Surgery operative.

Introduction

Bypass to the popliteal artery above the knee is a standard procedure, but the indications for this operation and which graft-material to use remain controversial issues. For above-knee bypass, the use of expanded polytetrafluoroethylene (ePTFE) is claimed to be as efficient as the use of autologous saphenous vein (SV). A Cochrane review concluded that there was no clear evidence for the preference of SV or ePTFE as a conduit for a bypass in this location.[1] Another recent review concluded that primary patency was superior after vein bypass compared to ePTFE.[2] However, the article did not analyse the influence on patency of different indications for the procedure. Five randomized controlled trials (RCTs) have been published with differing results.[3–7] Three of the studies showed no significant difference between graft materials after 4–5 years,[3,4,7] whereas the other two RCTs showed no difference up to 2 years but a significant advantage for SV thereafter,[4,6] Most of these studies suffered from small sample size and very few patients were eligible to 5-year follow-up. Furthermore, two of these studies were performed on patients with claudication only[4,7] and in the remaining RCTs the number of patients was not sufficient to permit a meaningful subgroup analysis to compare patients with critical ischemia vs. those with claudication. RCTs are not the only way to evaluate the outcome of

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surgery. Recent retrospective studies have challenged the effectiveness of synthetic bypass to the popliteal artery above the knee.[8,9]

In the Swedish vascular registry (Swedvasc), more than 90% of all vascular surgery is registered prospectively for more than 10 years.[10] A large number of unselected patients operated on in routine surgical care, with a minimum of 5-year follow-up, are available for study. The overall aim of the present study was to evaluate the results of the procedure in routine surgical care against the background of results reported from RCTs.

The specific aims were to answer the four questions: (i) what is the long-term patency with the two graft materials, (ii) do the long-term results differ depending on the indication for surgery, (iii) can risk factors predictive of failure/occlusion be identified and (iv) what are the consequences of a failed procedure.

Patients and Methods

Twenty-three hospitals in Sweden entered patients. These hospitals constitute 66% of all hospitals performing vascular surgery in Sweden. The Swedvasc registry was searched for all femoro-popliteal bypasses to the popliteal artery above the knee, which were performed in these hospitals in the years 1996 and 1997. Among 555 patient records, 499 (90%) with available records were studied. There were 56 further patients in the Swedvasc registry, whose records could not be retrieved and those were analysed separately, with use of data prospectively reported to the registry.

The analysis was performed between July 2002 and June 2003, i.e. 5–7 years after the operation. Case-records from the surgical and orthopaedic departments were reviewed and the intention was to re-examine all surviving patients without notification of an occlusion.

Thirty-nine characteristics (Table 1) for each patient were retrieved from the medical records and/or clinical follow-up. Results for 30 days, 1 year and at the time of the investigation were obtained. A graft was considered patent if there were clearly palpable distal pulses or pulse in a subcutaneous graft. Otherwise a duplex examination was requested. For dead patients, without a recorded occlusion, the graft was considered patent until the latest relevant examination that verified a patent graft, and follow-up was defined until that time-point.

Among the 303 surviving patients at the end of the study, 254 (84%) either had an occlusion registered in the case-records or were re-examined. The 49 patients who did not attend the clinical follow-up most were in poor health due to advanced age or co-morbid conditions or lived remote from the hospital. If a living patient, with no record of graft occlusion, did not attend for clinical follow-up we used the same definition for patency and follow-up period as for the deceased patients, i.e. follow-up ceased at the last verification of a patent graft in the patient records.

The composite end-point of graft failure included the following events:

1. Death within 30 days.
2. Graft occlusion.
3. Removal of an open graft due to infection.
4. Extension of the graft to below-knee position.
5. Amputation at below knee level or higher.

Surgical revisions and endoluminal dilatations of remaining valves or fistulae and of strictures were not class as procedure failure. Therefore, the principal outcome measure was assisted primary patency or addition of death within 30 days of operations.

The data were stored in a Microsoft Access™ database and the Statistica™ package was used for the calculations. Kaplan–Meier survival analysis was used together with the log-rank method for evaluation of significance. Independent variables predicting outcome or graft failure were identified by multivariate analysis through forward stepwise regression analysis and Cox's proportional hazard ratios. Categorical variable were analysed by χ^2 tests.

Results

The 499 patients included in the study had a median age of 73 years (range 42–96) and 88 (18%) were above 80 years of age at the time of the operation. The majority of patients (55%) were men. Women were slightly older (median 75 years) than men (72). Most patients (56%) were treated for critical ischemia but claudication was also common (44%). Twenty-eight percent of the patients had a SV graft and the remainder ePTFE. The proportion of SV grafts was similar among patients undergoing surgery for claudication and critical ischemia (Table 2). There were no significant differences in patient characteristics or in indications for surgery between the patients receiving SV or ePTFE grafts (Tables 2 and 3). Poor run-off (defined as 0 or 1 open crural artery) was more common in critical ischemia than in claudication (49 vs. 27%, $p<0.001$).

Table 1. Variables and definitions

Variable	Definitions and/or values
Personal id number	
Name	
Sex	
Side	
Indication	Claudication, rest pain or ulcer/small gangrene
Urgency	Planned or urgent
Order of procedure same location	Primary or secondary
Risk factors	
Cerebrovascular disease	Previous stroke or TIA
Diabetes	
Hyperlipemia	
Hypertension	
Cardiac disease	Coronary disease, atrial fibr., heart failure, valve disease
Pulmonary disease	
Renal disease	Serum creatinine >150 μg/l
Smoking	
Number of open crural arteries	Visible on angiography down to the ankle
Date of operation	
Graft material	ASV or ePTFE
Postoperative bleeding	
Graft infection	
Reoperation due to	Either open or endovascular procedure
Remaining valve of fistula	
Stricture	
Anastomotic narrowing	
Latest date of open graft	
Date of death	
Date of occlusion	
Symptoms after occlusion	Claudication converted to critical ischemia or not
Urgent reoperation after occlusion	
Date of amputation	

Mortality

Seven patients (1.4%) died within 1 month. At 1 year, 52 patients (10%) had died and by the end of the observation period 196 patients (39%) had died. Among patients above the age of 80 the mortality was 23% at 1 year and 65% at the end of the observation period. Almost 60% of these elderly patients lived more than 3 years.

Early complications

During the first postoperative month there were 26 (5.2%) occlusions. Postoperative bleeding occurred in 3.4% and infection in 1.8%. Early complication rates were independent of graft material. Later 40 patients underwent a revision for failing graft either with an open or an endovascular procedure: 22 had vein grafts and 18 had ePTFE and thus the frequency of revision was higher among SV-patients (16 vs. 5%; $p=0.0003$). However, the graft patency at the end of the observation period was not increased by graft revision (53% for primary assisted patency vs. 60% for primary patency; $p=0.36$).

Table 2. Indications in relation to graft material (within brackets percentage within each row)

	All patients	SV	ePTFE
Claudication	220	55 (25%)	165 (75%)
Rest pain	107	34 (32%)	73 (68%)
Ulcer/gangrene	172	50 (29%)	122 (71%)
All	499	139 (28%)	360 (72%)

Table 3. Characteristics of the patient groups (within brackets percentage of each column containing 139 SV and 360 PTFE patients, respectively)

	All patients ($N=499$)	SV ($N=139$)	PTFE ($N=360$)
Female sex	224	62 (45%)	162 (45%)
Mean age $\pm$SD	71 ± 9	72 ± 10	71 ± 9
Above 80 years (%)	88	26 (19%)	62 (17%)
Cerebrovasc. disease	58	18 (25%)	40 (11%)
Heart disease	260	68 (49%)	192 (53%)
Diabetes mellitus	153	44 (32%)	109 (30%)
No. of open crural arteries			
0	36	14 (10%)	22 (6%)
1	161	45 (32%)	116 (32%)
2 or 3	257	72 (52%)	185 (51%)
Urgent operation	39	13 (9%)	26 (7%)
Previous femoro-popliteal procedure	63	21 (15%)	42 (12%)

Results at the end of follow-up

At the end of follow-up 203 grafts (41%) had failed, according to our definition, (Table 4). Only two risk factors for failure were identified, namely graft material and the indication for surgery; poor run-off and urgent operation did not quite achieve statistical significance. The Cox proportional hazard ratios for these variables are shown in Fig. 1.

The success rate, according to indication for surgery, is shown in Fig. 2, with both types of graft material included. The success rate was higher for patients with claudication than for patients with critical ischemia ($p=0.0022$). The influence of the graft material on success rate according to indication for surgery is shown in Figs. 3 and 4. SV grafts performed better than ePTFE grafts in both situations (in critical ischemia $p=0.031$; Fig. 3, and in claudication $p=0.0027$; Fig. 4). Early results were similar but the curves separated after 6 months in patients with critical ischemia and after 1 year among patients with claudication.

A subgroup analysis of 88 patients above 80 years of age was performed. In this group, there were more women and cardiac disease was more common. The distribution of SV and ePTFE grafts was not different from that in the entire study. The proportion of failures was not greater than in younger patients (36 vs. 42%; $p=0.36$). There was no significant difference between SV or ePTFE grafts, perhaps due do the small number of patients ($p=0.29$, power 27%). The indication for surgery did not appear to influence results.

Symptom aggravation after a graft occlusion

Among the 220 patients undergoing surgery for claudication graft failure occurred in 79 patients. In 32 patients (41% of the occlusions) this was associated with deterioration of symptoms, compared to preoperative status, and in 33 (42%) an urgent reoperation was necessary. All, except one patient, with symptom aggravation had ePTFE grafts and all urgent reoperations were performed in patients with ePTFE grafts.

Table 4. Adverse events at the end of follow-up (within brackets percentage of each column containing 139 ASV and 360 PTFE patients, respectively)

	All patients	SV ($n=139$)	PTFE ($n=360$)
Revisions	40	22 (16%)	18 (5%)
Graft infection	9	3 (2%)	6 (2%)
Postoperative bleeding	17	10 (7%)	7 (2%)
Death within 30 days	7	2 (1.4%)	5 (1.4%)
Death at follow-up	196	61 (44%)	135 (38%)
Occlusions	172	30 (22%)	142 (39%)
Aggravation after occlusion*	32	1	31
Urgent reoperation*	33	0	33
Amputations†	61	15 (11%)	46 (13%)

* Only patients with claudication preoperatively.
† Twenty-four of those had no recorded occlusion.

Amputation

There were 61 amputations reported, 15 (11%) in patients with SV grafts and 46 (13%) in patients with ePTFE grafts (Table 4).

Analysis of patients lost to follow-up

In 56 patients, the case-records were unavailable. To identify whether these patients differed from those studied we used the information available in the ordinary Swedvasc registry, where data up to 1 year postoperatively are registered prospectively. The mean age and the indication for surgery in this group of patients lost to follow-up did not differ from those included in our study. However, synthetic grafts had been used more often (84 vs. 72%; $p=0.018$). Early failure (occlusion or death) was not significantly different from the main study (13.7 vs. 6.8%; $p=0.074$). Mortality at 1 year was similar for the lost to follow-up and included patients (12.5 vs. 10%; $p=0.63$).

Discussion

Most investigators of infra-inguinal bypass base their life-tables on graft patency or limb-salvage rates. However, there are other events that may be considered as procedural failures. Patients die in the immediate postoperative period and limbs may have to be amputated, even in the presence of a patent graft. Moreover, patent grafts sometimes become infected and have to be removed. Finally, an open bypass above-knee may require a revision to below-knee level. This is the rationale for use of the composite endpoint of graft failure.

Bypass to the popliteal artery above the knee with SV was found to be effective for relief of claudication, whereas bypass with ePTFE had lower success rates. In claudicants, graft occlusion led to the development of critical or acute ischemia in two fifths of the patients. For patients undergoing surgery for critical ischemia, long-term benefit of surgery was observed in two thirds of the patients with SV grafts but in less than half of those with ePTFE grafts. These findings are in agreement with two of the randomized trials.[4,5]

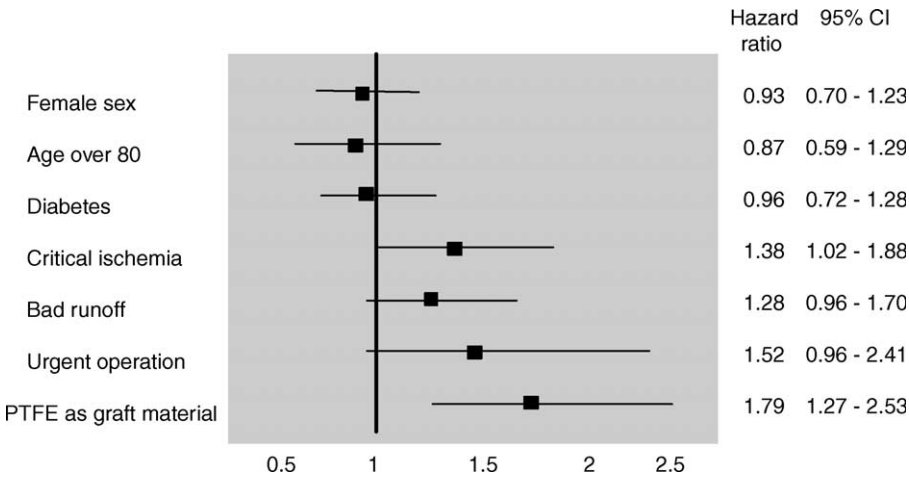

Fig. 1. Risk of graft occlusion; Cox's proportional hazard ratios for selected variables.

Therefore, our study shows that ordinary surgical care can obtain similar results to RCTs.

This study is retrospective and patients were not randomised. We did not control either the indication for surgery or the choice of graft material. However, the recorded demographic and clinical characteristics did not differ between the two groups and with caution the groups may be compared. The number of patients eligible for follow-up at 5 years was greater than in previously published RCTs[3–7] and the analysis of the patients lost to follow-up did not alter the conclusions drawn.

The determination of graft patency is a methodological problem in retrospective studies. A graft is not necessarily patent in patients where no occlusion has been reported. This study defined patency as a positive statement of patency in the case-records. There was no final follow-up of graft patency for deceased patients, allowing the possibility that results for both graft materials were slightly better than reported. It is unlikely that this would have affected the conclusions drawn.

Today patients with femoro-popliteal reconstruction may enter a graft surveillance program, leading to more frequent re-interventions in failing grafts. Therefore, we chose primary assisted patency as the outcome measure. However, interventions for occluded grafts also were common, especially for ePTFE grafts. We defined such reconstructions as failures. The use of assisted primary patency might favour SV reconstructions. We found that revisions were more common in SV patients than in ePTFE

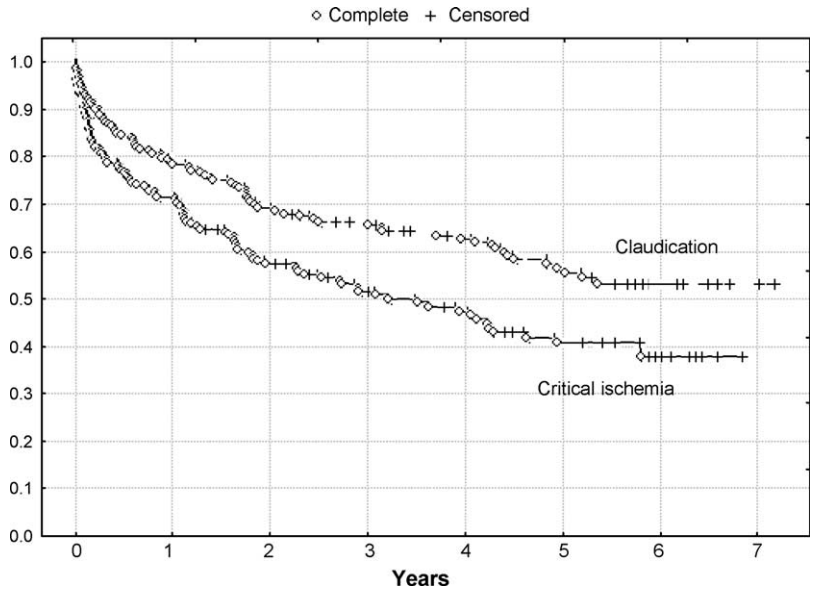

Fig. 2. Patency by indication for surgery ($p=0.0022$). Both graft materials are included.

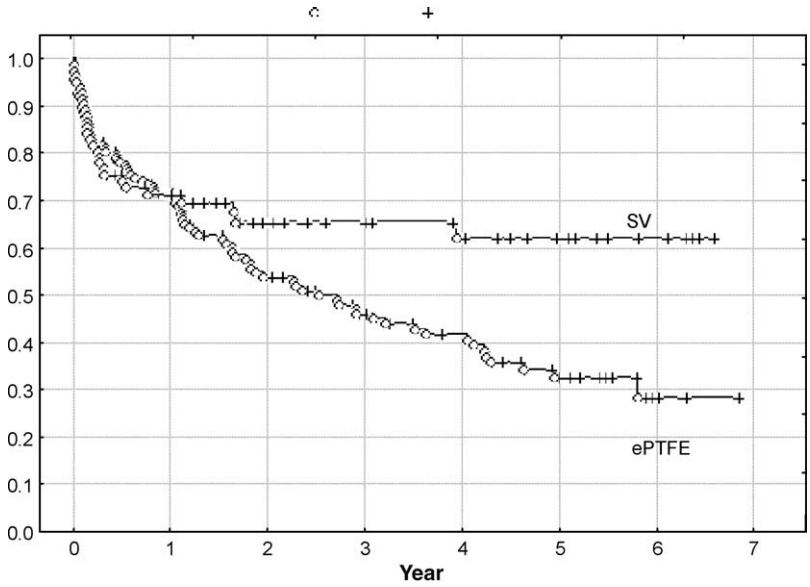

Fig. 3. Patency in relation to graft material for patients with critical ischemia ($p=0.031$).

patients but the results in patients with revised grafts tended to slightly worse. Thus, it is unlikely that the higher rate of revisions in patients with SV grafts resulted in an improved overall success rate.

We report similar success rates for patients operated on with ePTFE as in previous studies, both at 2–3 years[8,9,11] and 4–5 years.[3,11–15] Thus, differences between SV and ePTFE grafts could not be explained by poor results with the synthetic graft material in this particular study.

Since, results for SV and ePFTE grafts for treatment of critical ischemia were similar for the first 2 years, we speculated that ePTFE might be acceptable in elderly patients with a short life expectancy. In the subgroup analysis of patients above 80 years of age, we found that survival was better than anticipated. The technical results were similar to those of younger patients. The numbers in this very elderly group were small, leading to a risk of a type II statistical error. Nevertheless, we conclude that patients above 80 years of age should be treated in the same manner as younger patients.

The success rate was higher for patients with claudication than for those with critical ischemia. Claudication usually is a symptom in patients with

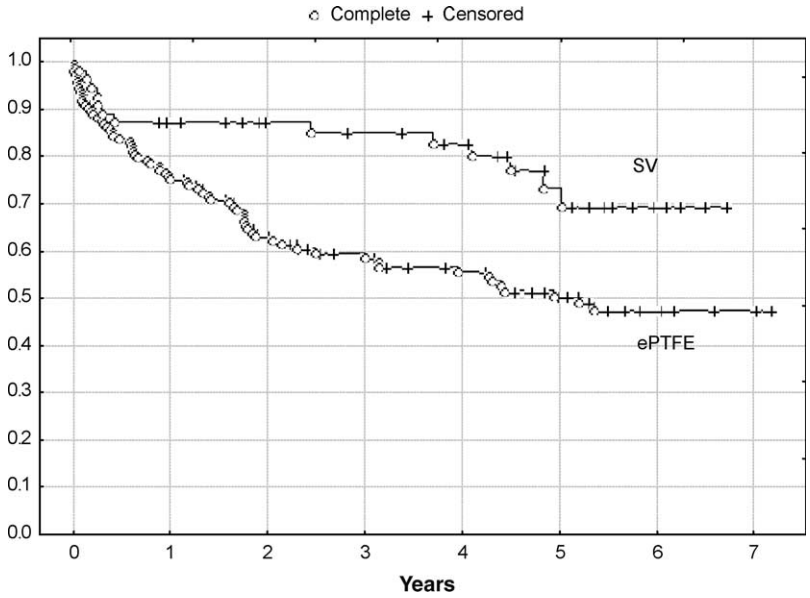

Fig. 4. Patency by graft material for patients with claudication ($p=0.0027$).

limited disease, predominantly occlusion of the superficial femoral artery, while in severe ischemia there are coexisting lesions often at several levels. The number of patent arteries in the lower leg was significantly higher in claudicants than in patients with critical ischemia, indicating a poorer run-off situation in the latter group. Hence, the success rate in critical ischemia being inferior, probably because the occlusion in the thigh was not the only significant lesion.

The reconstruction occluded in a third of the patients with claudication and the consequences of an occlusion were serious in a large proportion of those patients. Occlusion, with deterioration of symptoms, almost only occurred among patients with ePTFE grafts. Since, claudication is a benign condition, this study supports the view that, for this condition, the indications for surgery must be limited and that the use of ePTFE should be avoided.[8,11,14]

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